

PATENT COOPERATION TREATY

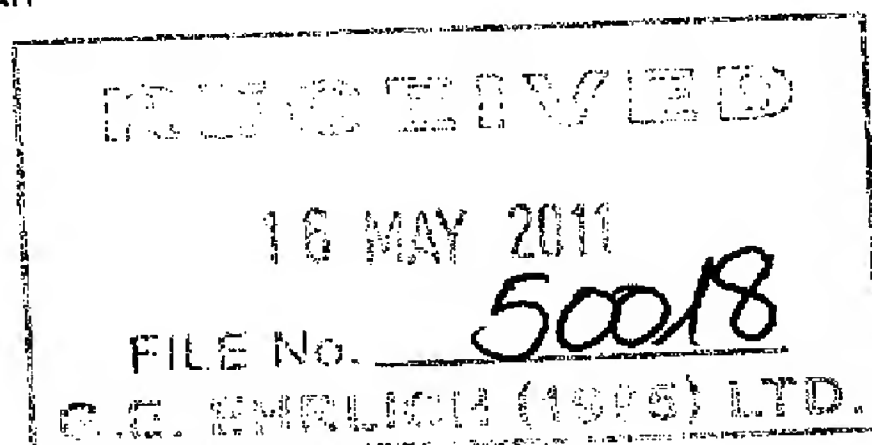
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From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

G.E. EHRLICH (1995) LTD.
11 Menachem Begin Road
52681 Ramat Gan
ISRAEL



NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

<p>Applicant's or agent's file reference 50018</p>	<p>Date of mailing (day/month/year) 09 May 2011 (09-05-2011)</p>
<p>International application No. PCT/IL2010/000985</p>	<p>International filing date (day/month/year) 24 November 2010 (24-11-2010)</p>
<p>Applicant CONTIPI LTD.</p>	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

<p>Name and mailing address of the International Searching Authority</p> <div style="text-align: center;"> </div> <p>European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016</p>	<p>Authorized officer</p> <p>RASMUSSEN, Sine Tel: +31 (0)70 340-4595</p>
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 50018	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/IL2010/000985	International filing date (<i>day/month/year</i>) 24/11/2010	(Earliest) Priority Date (<i>day/month/year</i>) 24/11/2009
Applicant CONTIPI LTD.		

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1A
☐ as suggested by the applicant
☒ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2010/000985

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-45

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2010/000985

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/010214 A2 (CONTIPI LTD [IL]; ZIV ELAN [IL]; GILAN JACOB [IL]; SINAI NIR [IL]; BAU) 24 January 2008 (2008-01-24) cited in the application page 9, line 15 - line 19; figures 14, 20 page 19, line 14 - line 19 page 36, line 25 - page 37, line 32 page 49, line 9 - line 18	1-45
X	WO 2005/087154 A2 (CONTIPI LTD [IL]; ZIV ELAN [IL]) 22 September 2005 (2005-09-22) cited in the application page 8, line 23 - page 11, line 19; figures 1,2,9-12	1-22, 25-45

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *8* document member of the same patent family

Date of the actual completion of the international search

24 February 2011

Date of mailing of the international search report

09/05/2011

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Neumann, Elisabeth

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2010/000985

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 2009/044394 A2 (CONTIPI LTD [IL]; ZIV ELAN [IL]; PERLE AMIR [IL]; HIRSCHOWITZ ERAN [IL]) 9 April 2009 (2009-04-09) cited in the application page 12, line 30 - page 14, line 20; figures page 21, line 23 - line 26 page 28, line 8 - line 32 -----</p>	<p>1-23, 25-45</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IL2010/000985

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2008010214	A2	24-01-2008	AU 2007274574 A1	24-01-2008
			CN 101511302 A	19-08-2009
			EP 2046241 A2	15-04-2009
			US 2009318750 A1	24-12-2009
WO 2005087154	A2	22-09-2005	AU 2005221424 A1	22-09-2005
WO 2009044394	A2	09-04-2009	EP 2214587 A2	11-08-2010
			US 2010217068 A1	26-08-2010

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-45

An apparatus for insertion into a human vagina for treating urinary incontinence, comprising a supporting section.

2. claims: 46, 47

A method of packaging an urinary incontinence device.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IL2010/000985

International filing date (day/month/year)
24.11.2010

Priority date (day/month/year)
24.11.2009

International Patent Classification (IPC) or both national classification and IPC
INV. A61F200

Applicant
CONTIPI LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Neumann, Elisabeth

Telephone No. +31 70 340-3028



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/L2010/000985

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/L2010/000985

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 46, 47

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 46, 47

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/L2010/000985

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-45

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>3, 5-8, 10-12, 16, 18, 24, 42-45</u>
	No: Claims	<u>1, 2, 4, 9, 13-15, 17, 19-23, 25-41</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-45</u>
Industrial applicability (IA)	Yes: Claims	<u>1-45</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/L2010/000985

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are 2 inventions covered by the claims indicated as follows:

1. claims: 1-45
An apparatus for insertion into a human vagina for treating urinary incontinence, comprising a supporting section.
2. claims: 46, 47
A method of packaging an urinary incontinence device.

The present application lacks unity within the meaning of Rule 13.2 of the PCT for the following reasons:

Document WO-A-2008010214 cited in the present search report discloses an apparatus for insertion into a human vagina for treating urinary incontinence, comprising a supporting section and an anchoring section.

Over this prior art the special technical features (in the meaning of PCT Rule 13.2) claimed in the application are:

Subject 1 (claims 1-18, 19-41, 42-43, 44-45): None.

Subject 2 (claims 46, 47): A method of packaging an urinary incontinence device.

No same or corresponding potential special technical feature can be found between any two of the above mentioned subjects. There is therefore no technical relationship involving same or corresponding potential special technical features between these two subjects. The inventions defined in the above mentioned subjects are thus not considered linked by a common inventive concept.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1 WO 2008/010214 A2 (CONTIPI LTD [IL]; ZIV ELAN [IL]; GILAN JACOB [IL]; SINAI NIR [IL]; BAU) 24 January 2008 (2008-01-24)
- D2 WO 2005/087154 A2 (CONTIPI LTD [IL]; ZIV ELAN [IL]) 22 September 2005 (2005-09-22)
- D3 WO 2009/044394 A2 (CONTIPI LTD [IL]; ZIV ELAN [IL]; PERLE AMIR [IL]; HIRSCHOWITZ ERAN [IL]) 9 April 2009 (2009-04-09)

1 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

1.1 Document D1 discloses (the references in parentheses applying to this document; see page 36, line 25 - page 37, line 32):

An apparatus (1400: figures 14A, 14B) for insertion into a human vagina for treating urinary incontinence, comprising:

a supporting section (1404) which renders sub-urethral support by actively providing a counter-force to at least a vaginal wall in response to a high stress event which causes medial deflection to at least the supporting section of the device (see item VIII, point 2).

1.2 Document D2 (see page 8, line 23 - page 11, line 19; figures 1,2,9-12) or document D3 (see page 12, line 30 - page 14, line 20; figures; page 21, line 23 - line 26; page 28, line 8 - line 32) each disclose all the technical features of claim 1 which is therefore not considered new (Article 33(2) PCT) in view of either D2 or D3.

2 INDEPENDENT CLAIM 19

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 19 is not new in the sense of Article 33(2) PCT.

2.1 Document D1 discloses (the references in parentheses applying to this document; see page 36, line 25 - page 37, line 32):

An apparatus (1400: figures 14A, 14B) for insertion into a human vagina for treating urinary incontinence, comprising:

an intermediate section (1402);

an anchoring section (1404, 1406: upper part) located on one side of the intermediate section provided with a plurality of beveled anchoring arms adapted to prevent movement of the apparatus into the vagina; and,

a supporting section (1404, 1406: lower part) located on the opposite side of the intermediate section from the anchoring section provided with a plurality of beveled supporting arms adapted to prevent movement of the apparatus out of the vagina and to provide sub-urethral support.

2.2 Document D2 (see page 8, line 23 - page 11, line 19; figures 1,2,9-12) or document D3 (see page 12, line 30 - page 14, line 20; figures; page 21, line 23 - line 26; page 28, line 8 - line 32) each disclose all the technical features of claim 19 which is therefore not considered new (Article 33(2) PCT) in view of either D2 or D3.

3 INDEPENDENT CLAIM 42

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 42 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1 Document D1 discloses (the references in parentheses applying to this document; see page 36, line 25 - page 37, line 32):

An apparatus for treating urinary incontinence, comprising: a deflection activated supporting section with a slope of 2.5 or lower (see item VIII, point 2), wherein the slope is the counter-force applied by the apparatus divided by the amount of medial deflection of the supporting section.

3.2 Document D2 (see page 8, line 23 - page 11, line 19; figures 1,2,9-12) or document D3 (see page 12, line 30 - page 14, line 20; figures; page 21, line 23 - line 26; page 28, line 8 - line 32) each disclose a deflection activated supporting section with a slope of claim 42 which is therefore not considered inventive (Article 33(3) PCT) in view of either D2 or D3 when taken alone.

4 INDEPENDENT CLAIM 44

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 44 does not involve an inventive step in the sense of Article 33(3) PCT.

4.1 Document D1 discloses (the references in parentheses applying to this document; see page 36, line 25 - page 37, line 32):

An apparatus for treating urinary incontinence, comprising: a supporting section which is suitable to render between 10 grams and 50 grams of sub-urethral support at rest.

4.2 Document D2 (see page 8, line 23 - page 11, line 19; figures 1,2,9-12) or document D3 (see page 12, line 30 - page 14, line 20; figures; page 21, line 23 - line 26; page 28, line 8 - line 32) each disclose a supporting section which is suitable to render between 10 grams and 50 grams of sub-urethral support at rest of claim 44 which is therefore not considered inventive (Article 33(3) PCT) in view of either D2 or D3 when taken alone.

5 DEPENDENT CLAIMS 2-18, 20-41, 43, 45

Dependent claims 2-18, 20-41, 43, 45 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see for example:

D2, page 8, line 23 - page 11, line 19; figures 1,2,9-12 for claims 2, 4, 13-15, 20-22, 25-41 (not new) and claims 3, 5-12, 16, 18, 43, 45 (not inventive).

D1, page 9, line 15 - line 19; figures 14, 20; page 19, line 14 - line 19; page 36, line 25 - page 37, line 32; page 49, line 9 - line 18 for claim 17 (not new).

Re Item VII

Certain defects in the international application

1 Independent claims 1, 19, 42 and 44 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1/D2) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

1 Although claims 1, 19, 42 and 44 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

2 The application does not meet the requirements of Article 6 PCT, because claims 1, 2, 4, 6 - 11, 13, 15, 17, 34 and 42 - 45 are not clear, the reasons are the following:

2.1 Claims 1, 44 and 45 do not meet the requirements of Article 6 PCT because the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

The only technical feature in claim 1 is the supporting section. The technical features how such a counter force is achieved is not claimed in claim 1.

The same reasoning applies for claims 44 and 45 whereby it is left open how the supporting section can render between 10 grams and 50 grams of sub-urethral support at rest or between 60 grams and 230 grams of sub-urethral support during a high stress event.

2.2 Equally, in claims 2 and 4 the maximal / minimal diameter is not further specified in order to achieve a desired counter-force. In addition, the counter-force is a measurement depending on the patient and is not a function of the apparatus itself.

2.3 As the high stress event of claims 6 - 8 is a parameter of the patient, the supporting section can only be deflectable up to a certain diameter in response to a high stress event.

2.4 The definition of "slope" is not clear in claims 9-11, 17, 42, 43 as it is determined by the counter-force applied by the apparatus divided by the amount of medial deflection. However, the parameter "force" is a function of the patient and is further not described by an angle- or elongation- unit but is measured in Newton. Therefore, Newton divided by a length (e.g. mm) will not result in a "slope"-unit.

2.5 Claims 13 and 15 do not comprise any technical features related to the apparatus of claim 1. Rather, it relates to a set of different apparatus'.

2.6 Claim 34 claims an applicator in addition to the apparatus. However, the applicator is not a technical feature of the apparatus. Claim 34 should be rather related to a set comprising an apparatus of claim 19 and an applicator adapted to store and deploy said apparatus into the vagina.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003